

Break out Group 3A

We have identified one gap for Component #3 of the AFSS.

1. Currently, the FDA has regulations that govern the controls used in the manufacturing, packaging, storage, and use of medicated animal feed. However, to have a comprehensive Animal Feed Safety System (AFSS), a broader regulatory approach may be required to address feed safety concerns associated with the manufacture, packaging, storage, distribution or use of non-medicated feed ingredients and mixed feed. The AFSS Team intends to consider the information gleaned from the public meetings and from responses to materials placed in the AFSS docket in its development of process control approach(es).

- Regulations should be based on the “end result.”
- Some agreed with the identified gap. Some agreed with this only with respect to the regulated industry segment, which is medicated feed. In this respect, the term, “process control” is wrong.
- Need to level the playing field
- Get basics in place for other segments
- FDA does not have authority to demand process controls by industry
- Problems with reactive approach vs. preventive approach to feed hazards:
 - What do consumers expect?
 - Do we only inspect for cause?
- Other segments of the feed industry: We lack verification for transportation segment, for example
- With limited regulatory resources, we should focus on hazards instead of quantity
- Process control is or is not equal to hazard identification and action to prevent or reduce exposure to hazards
- Safety assessment

Question 1) Do you agree with the identified gap? Why?

Yes, there is a discrepancy - FDA only regulates one segment of the feed industry proactively, the rest of the segments are controlled reactively. Is that the best way to run a feed safety system that looks forward?

Agree with need for process assessment or a safety assessment with appropriate “fixes” (Rx) built into the plan

Question 2) Do you disagree with the identified gap? Why?

- 1) Already have other acts in place like FD&C to deal with some problems, but acknowledged that they do not deal with all problems.
- 2) Problem is RX vs. proactive

Question 3) What gap(s) have we missed?

1) Identified safety issues need different solutions for different segments of the feed industry (different circumstances). Example: documentation needs will evolve over time and vary with the industry segment.

2) Lack regulations for problems not associated with non-medicated feed, transpiration, etc.

Question 4) What solution(s) do you recommend to fill the gap(s)?

- 1) Stakeholders meet with individual groups to develop reasonable guidance
- 2) 1st visit with education in mind
- 3) Penalize people into compliance

Question 5) How should the process control component incorporate agro terrorism concerns?

- 1) Registering facilities creates a list for good/bad
- 2) ID problems early without fear of retaliation
- 3) Recognition of this as a legitimate hazard
- 4) Hazards exist in all parts of the feed chain (industry)
- 5) ID vulnerability and limit access

Question 6) Would it be appropriate to recommend that firms develop written Standard Operating Procedures (SOPs) for the entire feed production process? Alternatively, would it be sufficient to recommend that firms develop written SOPs for only those process steps that directly impact the safety of the feed?

- 1) People who will write them for safety will see the value and do them for the rest of their process
- 2) Requirements should be safety-related
- 3) No More Regulations or not?

Question 7) How should the process control component incorporate feed safety-related transportation concerns for both incoming materials and the out-going product?

- 1) Requires integrated effort
- 2) Different risks with different ingredients
- 3) Accountability throughout the feed manufacturing chain
- 4) Prohibited material in dedicated trailers or cleanout certificates
- 5) SOPs enough or not enough?

Question 8) As envisioned, the Animal Feed Safety System addresses the labeling, production, distribution, and use of all feed ingredients and mixed feed regardless whether these products are produced at a commercial operation or on-farm. How should the process control component of the AFSS address the use (feeding) of feed ingredients and mixed feed on the farm? What type of on-farm controls should apply to animal feeding?

- 1) Not all industries are the same
- 2) Responsibility extends to packers for verification

- 3) Different focus when feed is fed vs. made?
- 4) It is possible to misuse a legitimately made product

- 5) Sampling v. inspection
- 6) What is the value of restricting access to certain ingredients to only certified/licensed users?